



Hepatitis C State Lab Testing Update

Rebecca Pelc, PhD, Virology/Serology Unit Manager, State Laboratory of Public Health
Rick Moore, MD, AAHIVS, Viral Hepatitis Medical Director

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What We'll Cover

1. Changes to Hepatitis C testing in the state lab
 - a) Transition from qualitative to quantitative HCV RNA testing
2. Interpretation of lab results
3. Next steps in evaluation of specific results

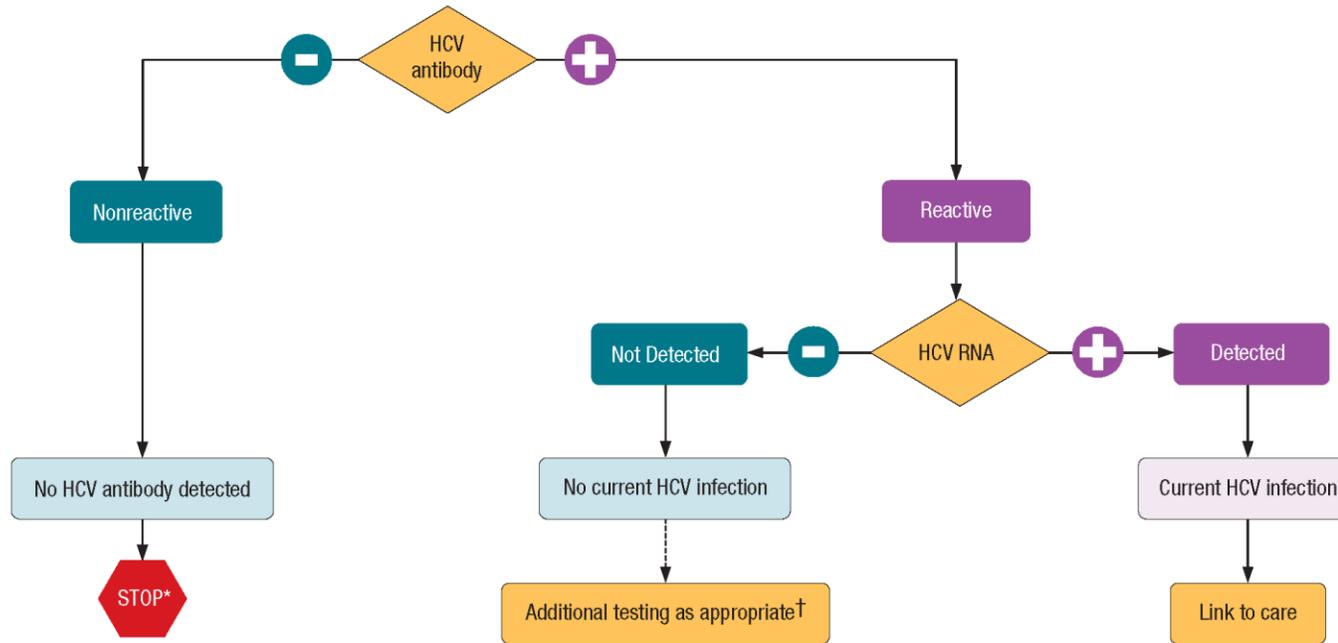
Testing at SLPH

Rebecca Pelc, PhD, Virology/Serology Unit Manager, State Laboratory of Public Health

Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention



* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

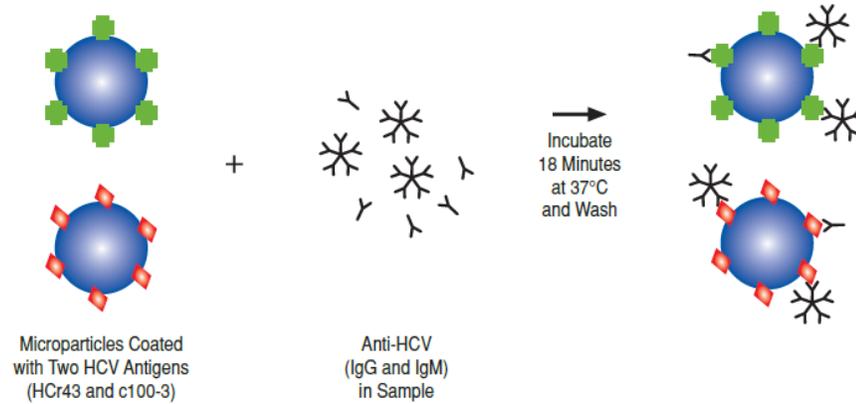
Source: CDC. Testing for HCV infection: An update of guidance for clinicians and laboratorians. *MMWR* 2013;62(18).



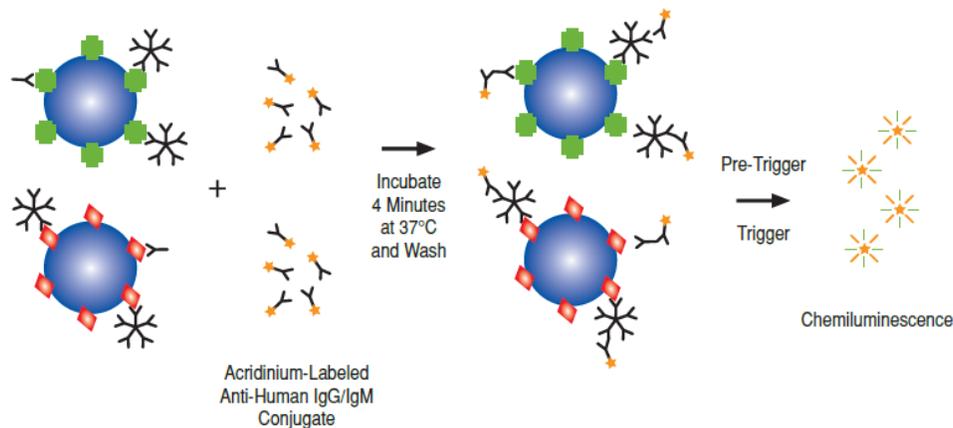
North Carolina
Public Health

Abbott Architect anti-HCV

Step 1 Sample Capture

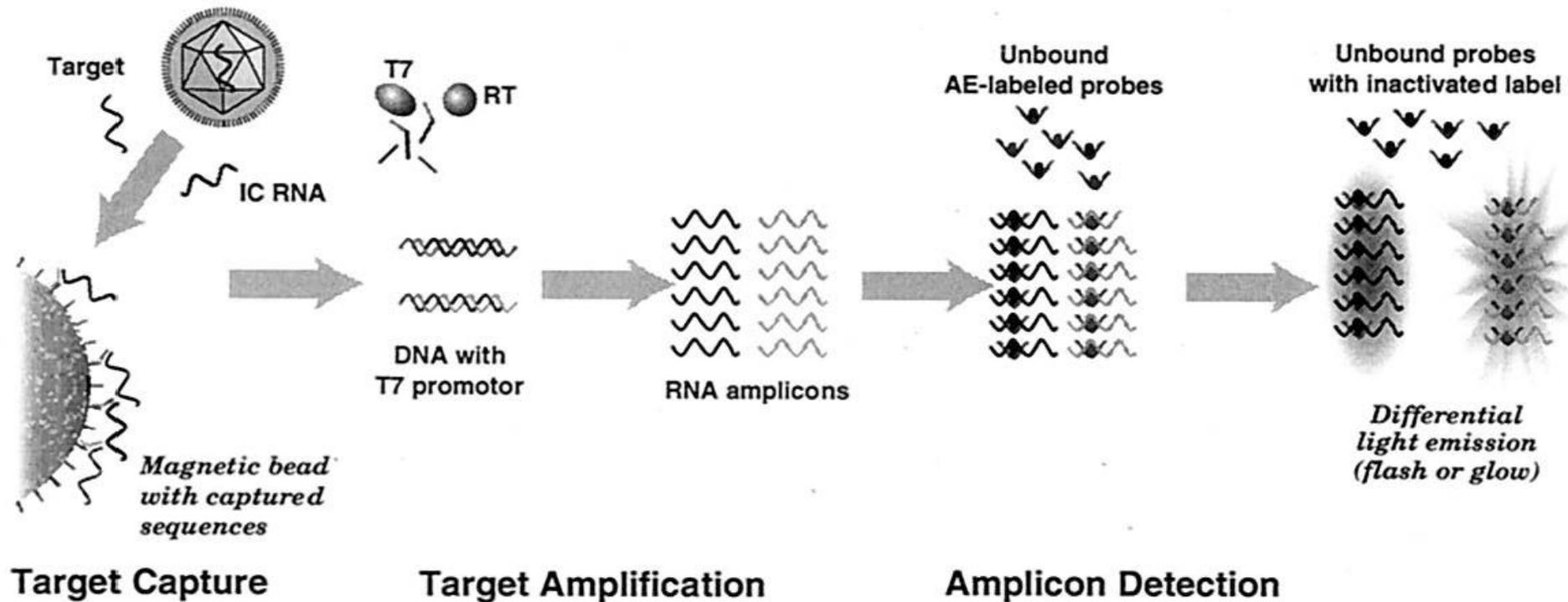


Step 2 Sample Detection



Slide Courtesy of Abbott Diagnostics

Transcription Mediated Amplification (Hologic)



Comanor, et al, *Am. Journal of Gastroenterology* 2001

Transcription Mediated Amplification (Hologic)



Effective 9/20/2021



What Is Not Changing

- Use of DHHS 1111 (filled out completely)
- 2-3 mL serum in pour-off tubes
- Specimens must be received cold within 5 days of collection or frozen on dry ice in red bags
- Labeling requirements for tubes (2 identifiers that match the form)
- Risk-based testing populations, prenatal, and >18
- Results mailed or available through CELR

Acceptance Criteria Not Met
Reason: _____
Date: _____ Initials: _____

HIV/HCV TESTING REPORT FORM
NC Department of Health and Human Services
State Laboratory of Public Health
4312 District Drive Raleigh, NC 27607-5490

Test Requested
 HIV HCV HIV and HCV

information

Last Name [grid]
First Name [grid] MI []
Address [grid]
Address [grid]
City [grid]

Attach Printed Label Below [large box]

County [] State [] Zip Code []



Interpreting Results

Rick Moore, MD, AAHIVS, Viral Hepatitis Medical Director

Hepatitis C RNA Quantitative Results

- Transitioning from qualitative positive/negative result to quantitative result
 - Will include numerical value and logarithmic value
- Will aid in Hepatitis C management and follow-up
 - Less need to repeat testing
 - Fulfills requirement of many insurances

Hepatitis C Ab Positive, RNA Positive

- Patient is Hepatitis C infected
- HCV RNA levels can be very high and do not correlate directly with disease activity
- Follow usual referral patterns for linkage to care
 - Can reach out to state-based bridge counselor program for assistance in treatment linkage
 - NC Drug User Health Guide:
https://epi.dph.ncdhhs.gov/cd/hepatitis/DrugUserHealthResourceGuide_04122021.pdf
 - Contains links to HCV-treating providers by region

Hepatitis C Ab Positive, RNA negative

- Consistent with either
 1. Prior infection with immune clearance
 2. Prior treatment success
- Individual considered uninfected
 - Not protected against future infection
- Caveat: If acute hepatitis suspected, consider repeating testing in 4-12 weeks

Hepatitis C Ab Positive, RNA < 10 det

- RNA is detected but not present in quantifiable level
- Recent or current symptoms?
 - Refer to Hepatitis C-Treating Provider
- Asymptomatic?
 - Repeat HCV RNA testing in 3-6 months

Hepatitis C Ab Equivocal

- Will reflex to Hepatitis C RNA
- Results can be managed with the same algorithms based on Hepatitis C RNA results

Questions?

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"BY THE WAY, I HAVE HEPATITIS C"

